

1 Dorian S. Berger, CA State Bar No. 264424  
Daniel P. Hipkind, CA State Bar No. 266763  
2 BERGER & HIPKIND LLP  
1880 Century Park East, Ste. 815  
3 Los Angeles, California 90025  
Telephone: 323-886-3430  
4 Facsimile: 323-978-5508  
Email: dsb@bergerhipskind.com  
5 Email: dph@bergerhipskind.com

6 *Attorneys for Plaintiff AIDS Healthcare*  
7 *Foundation, Inc.*  
8  
9

10 UNITED STATES DISTRICT COURT  
11 NORTHERN DISTRICT OF CALIFORNIA

12 **AIDS HEALTHCARE FOUNDATION,**  
13 **INC.,**

14 Plaintiff,

15 vs.

16 **GILEAD SCIENCES, INC.; JAPAN**  
**TOBACCO, INC.; JANSSEN SCIENCES**  
17 **IRELAND UC; AND JOHNSON &**  
**JOHNSON INC.,**

18 Defendants.  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

) Case No. 3:16-cv-00443-WHA  
)  
)

) Before Hon. William Alsup  
)  
)

) **JOINT CASE MANAGEMENT**  
) **STATEMENT AND [PROPOSED] ORDER**  
)

) Judge: Hon. William Alsup  
) Date: June 23, 2016  
) Time: 8:00 a.m.  
) Courtroom: 8  
)  
)  
)  
)

Pursuant to Fed. R. Civ. P. 26(f), Civil L.R. 16-9, the Standing Order on Contents Of Joint Case Management Statement, and the Court's April 28, 2016, Order (Dkt. No. 63), Plaintiff AIDS Healthcare Foundation, Inc. ("Plaintiff" or "AHF"), and Defendants Gilead Sciences, Inc. ("Gilead"), Japan Tobacco Inc. ("JT"), Janssen Sciences Ireland UC ("Janssen"), and Johnson & Johnson Inc. ("J&J") (collectively, "Defendants") (Plaintiff and Defendants collectively, "Parties") hereby submit this Joint Case Management Statement. Counsel for the Parties held a telephonic conference pursuant to Rule 26(f) on May 25, 2016.

# **I. JURISDICTION AND SERVICE**

The Complaint in this action was filed on January 26, 2016 against Gilead, JT, Japan Tobacco International U.S.A., Inc., ("JTI USA") and Emory University ("Emory"). Gilead was served on January 28, 2016. The named defendants filed motions to dismiss on March 21, 2016. *See* Dkt Nos. 29-38. Plaintiff dismissed defendant Emory without prejudice on April 8, 2016, Dkt. No. 49, and filed an Amended Complaint on April 11, 2016 adding as defendants Akros Pharma, Inc. ("Akros"), Janssen, and J&J. Dkt. No. 50. J&J was served on April 15, 2016. Janssen was served by mailing the Amended Complaint to J&J by certified mail on April 20, 2016. For purposes of this action only, Janssen does not dispute the adequacy of this method of service. Solely for purposes of this case, JT consented to service on May 12, 2016 pursuant to a Joint Stipulation dismissing without prejudice defendants Akros and JTI USA. Dkt. No. 74.

Plaintiff asserts federal question subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 1338 based on its causes of action under patent law, 35 U.S.C. § 1, *et seq.*, and antitrust laws, 15 U.S.C. §§ 1 and 2. Plaintiff further asserts standing to bring a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202. On May 16, 2016, Defendants filed motions to dismiss each of Plaintiff's causes of action. *See* Dkt Nos. 80-83. Defendants moved to dismiss the declaratory judgment claim under Rule 12(b)(1), arguing that Plaintiff lacks Article III and declaratory judgment standing. Defendants also moved to dismiss all of the claims under Rule 12(b)(6) on the ground that Plaintiff's Amended Complaint fails to state a claim upon which relief can be granted. This is the second set of motions to dismiss filed by Defendants. *See* Dkt Nos. 29-38. Plaintiff filed the Amended Complaint after the first set of motions to dismiss was filed.

Plaintiff asserts that venue is proper in this district under 28 U.S.C. § 1391 because Gilead's headquarters are in this District and a substantial part of the events giving rise to Plaintiff's claims occurred in this District and each Defendant is subject to personal jurisdiction in this District.

Plaintiff asserts that venue is further proper under 15 U.S.C. § 22 because Gilead's headquarters are in this District and all Defendants except JT transact business in this District. Defendants do not contest venue for purposes of this action.

## **II. FACTS**

### **Plaintiff's Statement:**

AIDS Healthcare incorporates by reference the Introduction and Background sections of its Opposition to Defendants' Motions to Dismiss the First Amended Complaint (Dkt. No. 87 at 1-13.) However, an overview of the facts alleged by AIDS Healthcare are recited below.

Gilead, in concert with Japan Tobacco, Inc. ("Japan Tobacco"), Janssen Sciences Ireland UC ("Janssen"), Johnson & Johnson, Inc. ("J&J") (collectively, "Defendants") undertook a monopolistic scheme that tied the sales of Tenofovir Alafenamide Fumarate ("TAF") to the sale of other drug products used in the treatment of HIV and AIDS. Gilead first released a similar Tenofovir-containing product, Tenofovir Disoproxil Fumarate ("TDF") 15 years ago in 2001. Gilead soon thereafter learned that TDF presented significant bone and kidney toxicity issues to patients taking TDF. Less than one year after the release of TDF, Gilead conducted human clinical trials showing that TAF presented a far safer alternative form of Tenofovir than TDF. However, in 2004, Gilead publicly claimed that it was abandoning its research and development of TAF. Despite this false claim, Gilead filed at least seven patent applications covering TAF and the use of TAF in the treatment of HIV between 2004 and 2005. Instead of promptly releasing TAF, Gilead waited until its patent exclusivity on the inferior TDF product was set to expire and released TAF in late 2015. By delaying the release of TAF, Gilead could continue to enjoy monopoly profits as the exclusive seller of TDF for a decade before releasing TAF, which is expected to displace the vast majority of TDF's sales due to its safety and superiority.

In the treatment of HIV and AIDS, physicians generally utilize multiple drugs in a Highly Active Antiretroviral Therapy ("HAART"). HAART therapies aim to reduce patients' viral loads,

1 thus maintaining patients' immune systems. To accomplish this, HAART regimens generally  
2 consist of three drugs: two Nucleoside Reverse Transcriptase Inhibitors ("NRTIs") and one drug  
3 from classes of drugs known as Non-Nucleoside Reverse Transcriptase Inhibitors ("NNRTI"),  
4 Protease Inhibitors ("PI"), or Integrase Nuclear Strand Transfer Inhibitors ("INSTI"). After TDF, a  
5 NRTI, was released in 2001, it became the backbone of many HAART regimens. While TDF was  
6 later released in combination with other drug products to form a variety of combined drug products  
7 (Atripla, Truvada, Stribild, and Complera), TDF was first released as a standalone product, which  
8 allowed physicians to customize HAART therapies for individual patients' needs by utilizing a  
9 variety of NNRTI, PI, and/or INSTI products in combination with TDF.

10 In contrast, when Gilead finally released TAF, it released only combination products.  
11 Genvoya, the first TAF-containing product released, ties the sale of TAF to three other drug  
12 products: elvitegravir, cobicistat, and emtricitabine. Gilead then released two other TAF-containing  
13 products: Odefsey, which ties the sale of TAF to emtricitabine and rilpivirine, and Descovy, which  
14 ties the sale of TAF to emtricitabine. To accomplish this tying scheme, Gilead entered into license  
15 agreements with Japan Tobacco and Janssen to license the rights to elvitegravir and rilpivirine,  
16 respectively, and share in the profits from the sale of these tied drug products. By tying the sale of  
17 TAF to these other drugs, Defendants are able to charge at premium levels for the drugs  
18 complementary to TAF despite a variety of competing NNRTI, PI, and INSTI products on the  
19 market, including generic, low-priced products. Further, physicians are deprived of the ability to  
20 tailor and customize HAART regimens based upon specific patient needs.

21 By releasing only combination products containing TAF, Gilead has insulated itself from  
22 generic competition in the market for TAF. The patents covering TAF are weak as TAF is merely a  
23 different, obvious prodrug formulation of Tenofovir, which was first discovered over 30 years ago.  
24 Accordingly, at the end of TAF's current five-year regulatory exclusivity period, a generic drug  
25 maker filing with the FDA an Abbreviated New Drug Application ("ANDA") challenging the  
26 validity of the TAF patents would likely enter the market quickly. However, Gilead has only  
27 released TAF in combination with other products, thereby forcing a potential generic maker  
28 interested in releasing a TAF-containing product to challenge all patents covering TAF and the tied

1 drugs. And because the patents covering the tied drugs are comparatively stronger than those  
 2 covering TAF, Defendants' tying scheme extends the length of time Gilead can enjoy exclusivity in  
 3 the TAF market.

4 Defendants' Statement:

5 This case concerns fixed-dose combination drugs that have become the "standard of care" for  
 6 treating HIV infection. A fixed-dose combination drug product is a single pill containing several  
 7 different active ingredients. For example, Gilead's Stribild® therapy contains a fixed combination of  
 8 four active ingredients that provides a complete HIV treatment regimen in one daily pill. Stribild®  
 9 has been the most popular HIV therapy in the United States for newly-diagnosed patients. In fact,  
 10 Gilead's top three HIV products are all fixed-dose combination tablets.

11 Late last year, Gilead started receiving FDA approval of its applications for improved  
 12 versions of its top HIV therapies, starting with Genvoya®. Genvoya® is a fixed-dose combination of  
 13 four drugs that replaces one of Stribild's active agents, known as "TDF," with a brand new, safer  
 14 drug called tenofovir alafenamide ("TAF") hemifumarate. AHF itself acknowledges TAF's lower  
 15 bone and kidney toxicity compared to TDF. The FDA approved the sale of Genvoya® in November  
 16 2015. The FDA subsequently approved Odefsey® and Descovy®, which are improved analogs of the  
 17 other two of Gilead's top-prescribed HIV regimens, in March and April of 2016, respectively.  
 18 Odefsey® and Descovy®, like Genvoya®, each replaces the TDF in its older analog with TAF.

<b>Genvoya®</b>	elvitegravir ("E"), cobicistat ("C"), emtricitabine ("F"), and TAF (together " <b>E/C/F/TAF</b> ")
<b>Descovy®</b>	emtricitabine (F) and TAF (together " <b>F/TAF</b> ")
<b>Odefsey®</b>	rilpivirine (R), emtricitabine (F), and TAF (together " <b>R/F/TAF</b> ")

22 In connection with the approval of Genvoya®, the FDA designated TAF a "new chemical entity"  
 23 ("NCE"), i.e., a new active ingredient never before approved. Accordingly, by statute, Gilead was  
 24 awarded five years of regulatory exclusivity, running to at least November 2020, during which time  
 25 no generic drug containing TAF (standalone or as part of a combination) can be approved by the  
 26 FDA ("NCE exclusivity").

1 Separately, the U.S. Patent Office determined TAF was novel and non-obvious (including as  
2 compared to TDF) and granted multiple patents covering TAF products, including U.S. Patent Nos.  
3 7,390,791, 7,803,788, 8,148,374, 8,633,219 and 8,754,065. The Patent Office also granted Gilead  
4 patents covering emtricitabine, but those patents are not at issue in this case. The other active  
5 ingredients in Genvoya<sup>®</sup> and Odefsey<sup>®</sup> are covered by patents assigned to JT (elvitegravir) and  
6 Janssen (rilpivirine), but those patents also are not at issue in this case. Gilead has entered into  
7 licensing agreements with JT and Janssen permitting Gilead to include elvitegravir and rilpivirine in  
8 Gilead's antiretroviral therapies.

9 These licensing agreements do not forbid Gilead from developing or marketing standalone  
10 TAF. Indeed, in January 2016, Gilead filed an application for FDA approval of standalone TAF  
11 with an indication for treatment of Hepatitis B ("HBV"). Based upon the FDA's goal of "acting on  
12 standard applications within 10 months," *see* 76 Fed. Reg. 56201-01, 56202 (Sept. 12, 2011), Gilead  
13 expects standalone TAF for HBV to be approved by November 2016. Although Gilead will not  
14 promote off-label use, once approved, physicians everywhere—including those working for  
15 Plaintiff—can prescribe TAF for HBV or for any purpose consistent with those physicians'  
16 independent medical judgments.

17 Plaintiff's Amended Complaint fails to allege facts upon which a claim for relief could be  
18 based, but Defendants principally dispute, among other things, any suggestion that they have  
19 conspired or otherwise agreed to any alleged tying of TAF to the other active ingredients in Gilead's  
20 fixed-dose combinations, or to anything else. With respect to allegations against Gilead alone,  
21 Gilead disputes the assertion that it manipulated the patent system and engaged in anticompetitive  
22 practices to prevent economical access to TAF. Gilead also disputes various irrelevant assertions in  
23 the Amended Complaint, including many directed to unrelated products and to diseases other than  
24 HIV.

25 Further Statement by Defendant JT

26 Defendant JT contends that the dispositive facts in this case are essentially undisputed.  
27 Gilead and JT entered into a License Agreement in 2005 which was subsequently amended several  
28 times. But neither the original 2005 License Agreement, nor any of its amendments contain any

provisions that require Gilead to tie the sale of TDF or TAF to the sale of elvitegravir. Nor do those agreements prohibit Gilead from marketing TDF or TAF on a standalone basis. Therefore, JT denies that it reached any unlawful agreement or conspired with Gilead, Janssen or J&J to delay the marketing of TAF or to tie the sale of any product to elvitegravir as alleged in the Amended Complaint.

#### Further Statement by Defendants Janssen and J&J

In 2014, Janssen and Gilead entered into a license agreement that allows Gilead to use Janssen's patented drug, rilpivirine, in a combination HIV treatment that also includes Gilead's patented drug, TAF. This combination treatment was approved by the FDA in March 2016, and is now marketed in the United States under the brand name Odefsey®. The Jansen-Gilead license agreement does not prohibit Gilead from developing other TAF products that do not include rilpivirine, including standalone TAF, at its discretion. Since entering the license agreement with Janssen, Gilead has launched two other TAF-containing HIV treatments that do not contain rilpivirine. Thus, customers, including AHF, can purchase TAF without rilpivirine.

### **III. LEGAL ISSUES**

#### Plaintiff's Statement:

Plaintiff contends that U.S. Patent Nos. 7,390,791; 7,800,788; 8,754,065; 8,148,374; and 8,633,219 are invalid under 35 U.S.C. §§ 101-103 and that Plaintiff has declaratory judgment standing under 28 U.S.C. §§ 2201 and 2202 to bring an action requesting a declaratory judgment of invalidity.

Plaintiff further contends that Gilead violates Section 2 of the Sherman Act (15 U.S.C. § 2), California Business & Professions Code § 17200, and the Nevada Unfair Trade Practices Act because it released TAF products only as combination products (Genvoya, Odefsey, and Descovy) that tie TAF with four other drugs used in the treatment of HIV (elvitegravir, cobicistat, emtricitabine, and rilpivirine) in an effort to illegally utilize Gilead's monopoly over TAF to profit from the sales of the other tied drugs and to prolong Gilead's monopoly over TAF by making it more difficult for generic manufacturers to enter the TAF market. Plaintiff contends that all Defendants violate Section 1 of the Sherman Act (15 U.S.C. § 1), the California Cartwright Act, California



1 Business & Professions Code § 17200, and the Nevada Unfair Trade Practices Act because JT,  
 2 Janssen, and J&J entered into license agreements with Gilead to license the use of drugs combined  
 3 with TAF.

4 Defendants' Statement:

5 Defendant Gilead asserts that no case or controversy exists between Gilead and Plaintiff  
 6 AHF regarding patent infringement, and therefore this court lacks subject matter jurisdiction to  
 7 adjudicate the validity of the '791, '788, '065, '374, and '219 patents. Because AHF has not made  
 8 any meaningful preparations to infringe the patents-in-suit and because Gilead has not committed  
 9 any affirmative act that could give rise to a dispute between it and AHF regarding those patents, the  
 10 requisite immediacy and reality to form an Article III case or controversy is missing. *MedImmune,*  
 11 *Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). AHF also fails to state a claim of patent invalidity.

12 Defendant Gilead also asserts that AHF's various antitrust and unfair competition claims fail.  
 13 Count II of the Amended Complaint, AHF's Sherman Act § 2 claim, fails for at least three reasons.  
 14 First, AHF fails to allege facts suggesting that Gilead possesses monopoly power in a relevant  
 15 market. Second, Plaintiff fails to plead facts suggesting any anticompetitive conduct by Gilead.  
 16 Third, Plaintiff fails to allege facts suggesting any causal antitrust injury. Count III, AHF's  
 17 conspiracy to monopolize claim, fails for the same reason as Count II noted above.

18 Count IV, AHF's conspiracy to tie claim, fails for at least four independent reasons. First,  
 19 because the alleged tying product (TAF) cannot lawfully be sold by itself, AHF is unable to plead  
 20 that Gilead has any market power with respect to the alleged tying product (TAF). And once  
 21 standalone TAF is approved for HBV, AHF still will not be able to state a claim for tying because  
 22 there can be no tying where the alleged tying product is sold separately. Second, because standalone  
 23 TAF cannot lawfully be sold, AHF cannot plead that there exists a distinct market for standalone  
 24 TAF. Third, AHF is unable to plead causal antitrust injury. Fourth, AHF is unable to plead facts  
 25 suggesting any agreement by Defendants to tie.

26 Counts V, VI, and VII—alleging violations of California's Cartwright Act, California's  
 27 Unfair Competition law, and Nevada's Unfair Trade Practices Act, respectively—are all premised  
 28 upon the alleged antitrust violations outlined above. Because AHF's Sherman Act claims fail, its



1 state-law claims necessary fail as well.

2 Further Statement by Defendant JT

3 Defendant JT. asserts that Plaintiff lacks standing to sue to declare the ‘219 Patent is invalid  
4 because Declaratory judgment jurisdiction exists only where there is a controversy of sufficient  
5 “immediacy and reality” to create a justiciable controversy, i.e., (1) an injury-in-fact, i.e., a harm that  
6 is concrete and actual or imminent, not conjectural or hypothetical, (2) that is fairly traceable to the  
7 defendant’s conduct, and (3) can be redressed by a favorable decision.. Here, Plaintiff has failed to  
8 allege any concrete, actual or imminent harm to it that is traceable to JT’s conduct concerning any of  
9 the patents identified in Count I of the Amended Complaint, particularly the ‘219 Patent.

10 Defendant JT also asserts that the alleged conspiracy between it and its licensee, Gilead, is  
11 implausible and impossible as a matter of law. First, a patent holder cannot conspire with its  
12 licensee unless the relationship “deprives the marketplace of independent sources of economic  
13 power previously pursuing separate interests.” Here, JT and Gilead were not in a position to compete  
14 in the alleged relevant market prior to entering the 2005 License Agreement.

15 Moreover, JT and Gilead did not agree in 2005 or any other time, that Gilead would tie the  
16 sale of TAF to elvitegravir when it brought Genvoya to the market in 2015. Neither the 2005 License  
17 Agreement nor its amendments contains any such requirement. Gilead does not unlawfully tie the  
18 sale of TAF to elvitegravir because TAF is not a separate product market in which Gilead has market  
19 power to use TAF as a tying product. Combinations including TAF compete with other HIV  
20 therapies. And Gilead markets TAF in combinations of drugs without elivitegravir.

21 Finally, Gilead is not approved to market TAF on a standalone basis so there can be no  
22 unlawful tying of TAF to other drugs.

23 Further Statement by Defendants Janssen and J&J

24 AHF alleges that Gilead, on one hand, and Janssen and J&J, on the other, violated Section 1  
25 of the Sherman Act, 15 U.S.C. § 1, by allegedly conspiring to tie the availability of TAF to Janssen’s  
26 rilpivirine. Janssen and J&J assert that AHF fails to state a plausible Section 1 claim against them  
27 for at least three independently sufficient reasons. First, the Amended Complaint lacks any factual  
28 allegations to support the conclusory assertion that Janssen and Gilead conspired to restrain trade.

1 *See Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556  
 2 (2007); *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1047 (9th Cir. 2008); *Apple Inc. v. Psystar*  
 3 *Corp.*, 586 F. Supp. 2d 1190, 1195 (N.D. Cal. 2008) (Alsup, J.). Second, AHF cannot allege any  
 4 harm to competition in the market for rilpivirine (the allegedly “tied” product), since rilpivirine is  
 5 protected by valid, enforceable patents but is available to purchase from Janssen as a standalone  
 6 product. *See Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1200 (9th Cir. 2012); *Blough v.*  
 7 *Holland Realty, Inc.*, 574 F.3d 1084, 1092 (9th Cir. 2009). Third, sales of rilpivirine are not tied to  
 8 sales of TAF (the allegedly “tying” product) because TAF is available in two formulations that do  
 9 not contain rilpivirine and will soon be available in standalone form if approved by the FDA, and  
 10 therefore no one wanting TAF is forced to purchase rilpivirine. *See Cascade Health Solutions v.*  
 11 *PeaceHealth*, 515 F.3d 883, 912 (9th Cir. 2003) (citing *Eastman Kodak Co. v. Image Technical*  
 12 *Servs., Inc.*, 504 U.S. 451, 461 (1992)) (tying exists where “the seller conditions the sale of one  
 13 product (the tying product) on the buyer’s purchase of a second product (the tied product)”).

14 AHF’s claims against Janssen and J&J under the California Cartwright Act, the California  
 15 Unfair Competition Law Section 17200, and the Nevada Unfair Trade Practices Law are all  
 16 premised on its defective tying allegations, and therefore fail along with the Section 1 claim against  
 17 Janssen and J&J.

#### 18 **IV. MOTIONS**

19 Defendants’ second motions to dismiss under Rules 12(b)(1) and 12(b)(6) are currently  
 20 pending. *See* Dkt. Nos. 80-81, 83, 87, 89-91. If those motions are not granted, the parties anticipate  
 21 filing motions for summary judgment.

#### 22 **V. AMENDMENT OF PLEADING**

23 Plaintiff filed its Amended Complaint on April 11, 2016. (Dkt. No. 50.) Plaintiff proposes  
 24 90 days after Defendants file answers as the deadline for amending the pleadings.

#### 25 **VI. EVIDENCE PRESERVATION**

26 Counsel have met and conferred regarding preservation of evidence, including electronic  
 27 evidence, and have taken measures with their respective clients to preserve relevant materials in  
 28 accordance with the Federal Rules of Civil Procedure. The parties have reviewed the Guidelines

1 Relating to the Discovery of Electronically Stored Information (“ESI Guidelines”).

2 **VII. DISCLOSURES**

3 The parties propose 21 days after the Court enters an Order regarding Defendants’ Motions  
4 to Dismiss the Amended Complaint as the deadline to serve initial disclosures.

5 **VIII. DISCOVERY**

6 No formal discovery has taken place yet. The Parties met and conferred pursuant to Fed. R.  
7 Civ. P. 26(f) on May 25, 2016 and have agreed that no formal discovery shall commence at least  
8 until the Court has entered an Order denying or denying-in-part Defendants’ Motions to Dismiss the  
9 Amended Complaint (if denied in part, then discovery may commence concerning those claims on  
10 which Defendants’ motions to dismiss are denied; if granted with leave to amend, then discovery  
11 may remain stayed pending resolution of any further motions to dismiss). Because of the uncertainty  
12 around when the pleading stage of this case will conclude, the Parties propose meeting and  
13 conferring within five business days following the Court’s Order on Defendants’ Motions to  
14 Dismiss the Amended Complaint and, if necessary, submitting an Amended Case Management  
15 Statement within 14 days of the date of the Court’s Order on Defendants’ Motions to Dismiss the  
16 Amended Complaint with a proposed discovery schedule.

17 The parties do not propose altering the limitations on discovery contained in the Federal  
18 Rules of Civil Procedure at this time.

19 The parties agree to submit a stipulated e-discovery order.

20 **IX. CLASS ACTIONS**

21 At this time, Plaintiff does not intend to seek certification of a class.

22 **X. RELATED CASES**

23 The parties are unaware of any cases related to this action.

24 **XI. RELIEF**

25 Plaintiff seeks (1) a declaration that U.S. Patent Nos. 7,390,791; 7,800,788; 8,754,065;  
26 8,148,374; and 8,633,219 are invalid; (2) injunctive relief; (3) monetary damages in accordance with  
27 Federal, California, and Nevada antitrust laws, and entry of a judgment against Defendants; (4)  
28 recovery of costs of this action, including attorneys’ fees, as provided by law; (5) award of pre-

1 judgment and post-judgment interest; and (6) any other and further relief as required by equity and  
2 justice.

3 **XII. SETTLEMENT AND ADR**

4 No ADR efforts have taken place to date. As required by L.R. 16-8 and Local ADR Rule 3-  
5 5, the parties met and conferred by telephonic conference to attempt to agree on an ADR process on  
6 May 25, 2016, and counsel for all parties have filed ADR Certifications. Because the parties  
7 disagree on the likelihood of claims surviving the currently-pending motions to dismiss, the parties  
8 propose meeting and conferring further to attempt to agree on an ADR process, if necessary, within  
9 five business days following the Court's Order on Defendants' Motions to Dismiss the Amended  
10 Complaint, and filing either a "Stipulation and (Proposed) Order Selecting ADR Process" or a  
11 "Notice of Need for ADR Phone Conference" within 14 days of the date of such Order, as required  
12 by L.R. 16-8 and Local ADR Rule 3-5.

13 **XIII. CONSENT TO MAGISTRATE JUDGE FOR ALL PURPOSES**

14 Not all parties consented to have this matter heard by a Magistrate Judge.

15 **XIV. OTHER REFERENCES**

16 The parties agree that this case is not suitable to binding arbitration, a special mater, or the  
17 Judicial Panel on Multidistrict Litigation.

18 **XV. NARROWING OF ISSUES**

19 The parties agree that aside from the motions to dismiss discussed *supra* at Part IV, it is  
20 premature to address this topic.

21 **XVI. EXPEDITED TRIAL PROCEDURE**

22 The parties agree that this case is not suitable for handling on an expedited basis with  
23 streamlined procedures.

24 **XVII. SCHEDULING**

25 The Parties agree that it is premature to set a schedule at least until an initial Order on  
26 Defendants' Motions to Dismiss the Amended Complaint is issued. The Parties propose submitting  
27 a further Case Management Statement within 14 days of such Order proposing a case schedule.  
28

**XVIII. TRIAL**

Plaintiff has demanded a jury trial, and the Parties preliminarily estimate that the trial of this action would take approximately 10-15 court days assuming that the issues in the case are not narrowed

**XIX. DISCLOSURE OF NON-PARTY INTERESTED ENTITIES OR PERSONS**

The parties each have or will file a “Certification of Interested Entities or Persons” per L.R. 3-15 before the Initial Case Management Conference.

**XX. PROFESSIONAL CONDUCT**

Attorneys of record for all parties have reviewed the Guidelines for Professional Conduct for the Northern District of California.

**XXI. OTHER MATTERS**

Counsel for Gilead intends to provide opportunities to junior lawyers (six years or fewer years out of law school) to argue motions in court, to take depositions, and to examine witnesses at trial. However, given the paucity of factual allegations in the amended complaint and the fact that the parties have stipulated that there will be no discovery at least until the Court rules on the motions to dismiss, it is unclear what form those opportunities may take and when they may arise. Although the amended complaint identifies few potential deponents, counsel for Gilead currently expects that associate Yite John Lu (class of 2011) will depose one or more of Otto Yang, Michael Wohlfeiler, or Robert Heglar, for example, depending on how the facts develop and whether certain claims survive the motions to dismiss. Counsel also expects Mr. Lu to argue discovery-related motions that may arise. Should this case proceed, counsel for Gilead will be able to further identify for the court specific opportunities it intends to provide junior lawyers. Gilead embraces significant, hands-on involvement by junior attorneys and we therefore do not anticipate any need to require Gilead’s attendance at the upcoming case management conference where this subject might be discussed.

Counsel for JT, Janssen and J&J also intend to provide opportunities for junior lawyers, including taking and defending depositions, arguing motions in court, and examining witnesses at trial. Counsel for JT, Janssen and J&J concur with counsel for Gilead that, at this stage of the case, it is unclear what form those opportunities may take and when they may arise. Should any claims

1 against Janssen and J&J proceed and depending on how the facts develop, counsel for Janssen and  
 2 J&J currently expect that associates Kade N. Olsen (class of 2013) and Jacob F. Siegel (class of  
 3 2015) will have opportunities to participate in depositions such as those referenced by counsel for  
 4 Gilead, as well as to argue discovery-related motions that may arise. Should any claims against their  
 5 clients proceed, counsel for JT, Janssen and J&J will be able to further identify for the court specific  
 6 opportunities they intend to provide junior lawyers. Since JT, Janssen and J&J embrace significant  
 7 involvement by junior lawyers, counsel for JT, Janssen and J&J do not believe the presence of client  
 8 representatives at the case management conference would be useful for purposes of discussing this  
 9 subject at this time.

10 Dated: June 16, 2016

BERGER & HIPSKIND LLP

11 By: /s/ Daniel P. Hipskind

12 Daniel P. Hipskind  
 13 Attorneys for Plaintiff AIDS Healthcare  
 14 Foundation, Inc.  
 15  
 16  
 17

18 Dated: June 16, 2016

IRELL & MANELLA LLP

19 By: /s/ Gary N. Frischling

20 Gary N. Frischling  
 21 Attorneys for Defendant  
 22 Gilead Sciences, Inc.  
 23

24 Dated: June 16, 2016

HOLLAND & KNIGHT LLP

25 By: /s/ Jerome W. Hoffman

26 Jerome W. Hoffman  
 27 Attorneys for Defendant  
 28 Japan Tobacco Inc.

Dated: June 16, 2016

PATTERSON BELKNAP WEBB & TYLER LLP

By: /s/ William F. Cavanaugh, Jr.

William F. Cavanaugh, Jr.  
Attorneys for Defendants  
Janssen Sciences Ireland UC and  
Johnson & Johnson, Inc.



**ATTESTATION CLAUSE**

I, Daniel P. Hipskind, am the ECF user whose identification and password are being used to file the foregoing JOINT CASE MANAGEMENT STATEMENT AND [PROPOSED] ORDER. In compliance with Local Rule of Civil Procedure 5-1(i)(3), I hereby attest that Gary N. Frischling, Jerome W. Hoffman, and William F. Cavanaugh, Jr., have concurred in the filing of this document.

Dated: June 16, 2016

/s/ Daniel P. Hipskind

Daniel P. Hipskind

**CASE MANAGEMENT ORDER**

The above JOINT CASE MANAGEMENT STATEMENT & PROPOSED ORDER is approved as the Case Management Order for this case and all parties shall comply with its provisions. [In addition, the Court makes the further orders stated below:]

DATED: \_\_\_\_\_  
The Honorable William Alsup  
United States District Judge